

REMARKS

Claims 1-6 are pending in the instant application. The Examiner has withdrawn claims 7-19 as being directed to non-elected subject matter. Applicants expressly reserve the right to file divisional applications to the subject matter not currently being pursued.

Claims 1-3 have been amended to clarify Applicants' invention. Specifically, Formula I in Claim 1 has been amended to fix the position of substituent R⁵. Additionally, Claims 1-3 have been amended so that substituent R³ allows optional substitution of the alkyl definition with OR, where R is H or C₁-C₁₀ alkyl. Claims 1-3 have also been amended so that R⁵ is not defined as hydrogen. Support for these amendments can be found in the specification and the specific compounds exemplified.

RESTRICTION REQUIREMENT

In the previous office action, the Examiner maintained the restriction requirement and indicated that Claims 1-6, where R² is -N(R³)₂ or -OR³ and R³ is H or C₁-C₁₀ alkyl, have been examined. The Examiner had withdrawn Claims 7-19 and the remaining subject matter of Claims 1-6 as being drawn to non-elected subject matter.

In the present office action, the Examiner has stated that a new restriction requirement is needed. Applicants respectfully traverse this restriction requirement. The Examiner has indicated that the new restriction requirement is based on the alleged "new prior art". However, Section 803 of the M.P.E.P. states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions." Additionally, Section 803 provides:

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (1) The inventions must be independent or distinct as claimed;
and
- (2) There must be a serious burden on the examiner if
restriction is required.

Applicants assert that there would be no serious burden on the Examiner in searching the claims using the core structure depicted in Formula I of the instant invention. Applicants believe that the current scope of the claims, prior to this restriction, would fall within one classification and one field of searching. Therefore, Applicants contend that the Examiner should examine all of the subject matter of the current claims of the instant invention since there would be no serious burden on the Examiner. For the reasons noted above, Applicants respectfully request that the restriction requirement be withdrawn.

35 U.S.C. 112, second paragraph

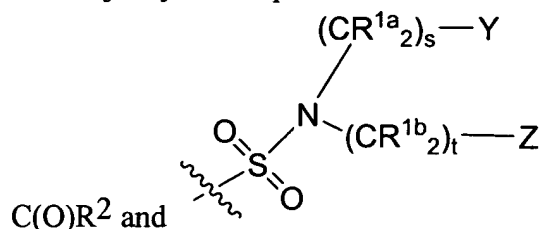
The Examiner has rejected Claims 1-3 and 6, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Examiner has stated that substituents R³ and R⁷ are mutually dependent. In order to clarify the instant invention, Applicants have amended Claim 1 and 3, so that R³ is defined as hydrogen and C₁-C₁₀ alkyl, where alkyl is optionally substituted with OR, where R is H or C₁-C₁₀ alkyl. Applicants contend that the OR definition is supported by the OR³ definition of R⁷, since R³ is defined as H or C₁-C₁₀ alkyl. Applicants assert that no new matter is being added as there is support for this amendment in the application, including the original claims and the specific compounds depicted in the experimentals. Therefore, Applicants respectfully request that this rejection be withdrawn.

SECTION 102

The Examiner has rejected Claims 1-3 and 6 under 35 U.S.C. 102(b) as allegedly being anticipated by US Patent No. 3,180,875 ('875). The Examiner has stated that the '875 patent discloses a specific compound that allegedly reads on the instantly claimed genus. Applicants respectfully traverse this rejection. For a single reference to anticipate an invention, the reference must, either expressly or inherently, disclose each and every element of the claimed invention. *RCA Corp. v. Applied Digital Data Sys., Inc.*, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984).

Applicants respectfully request that the Examiner clarify as to which compound, (column and line number), the Examiner is citing as allegedly anticipating the instant claims.

The compounds disclosed in the '875 patent are dithiobis[indole-2-carboxylic acid] derivatives. The majority of compounds contain a dithio bridge. Other compounds do not contain the



substitutions that are required in the instant invention.

The compounds depicted in '875 possess either an SO or dithio bridge; they do not contain S(O)₂. Additionally, unlike the instant invention, all of the indole-containing compounds shown in '875 require that the nitrogen atom of the indole be substituted, specifically with alkyl. Applicants contend that the '875 reference does not disclose compounds which contain each and every element of the instant invention and do not anticipate the claims. Therefore, Applicants respectfully request that this rejection be withdrawn.

The Examiner has also rejected Claims 1-3 and 6 as allegedly being anticipated by Szmuszkovic, *Journal of Organic Chemistry (JOC)*. The Examiner has pointed to a specific compound as allegedly anticipating the instant invention. However, as noted above, each and every element of the instant invention must be disclosed in this reference for it to anticipate the invention. Unlike the instant invention, the compound cited by the Examiner does not allow for substitution on the phenyl of the indole ring. The instant invention requires that R⁵ be fixed and is not hydrogen. Applicants contend that the Szmuszkovic *JOC* article does not anticipate the instant invention since it does not disclose each and every element of the Claims. Therefore, Applicants respectfully request that this rejection be withdrawn.

SECTION 103

The Examiner has indicated that Claims 1-3 and 6 are rejected under 35 U.S.C. 103 as allegedly being unpatentable over US Patent No. 3,180,875 ('875) and Szmuszkovic, *Journal of Organic Chemistry (JOC)*.

Applicants respectfully traverse this rejection. Applicants note that '875 patent is directed to derivatives of 3'-3'-dithiobis[indole-2-carboxylic acid]dihydrazines. The patent is related to an invention that is useful for preparing novel organic compounds. Applicants respectfully assert that the '875 patent is non-analogous art. According to the CAFC, in *In re*

Deminski, 796 F.2d 436 (CAFC 1986), there is a two step process for determining if a reference is non-analogous art. As stated by the *Deminski* Court, 796 F.2d at 441,

First, we decide if the reference is within the field of the inventor's endeavor. If it is not, we proceed to determine whether the reference is reasonably pertinent to the particular problem with which the inventor was involved.

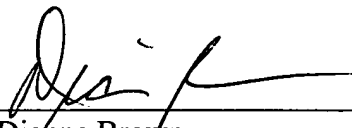
Applicants respectfully contend that a reference simply dealing with organic compounds, specifically the preparation of 3'-3'-dithiobis[indole-2-carboxylic acid]dihydrazines, would not be in the field of one with ordinary skill in oncology. Applicants point out that there is no discussion with respect to the utility of the compounds disclosed in the '875 patent. Applicants assert that this reference would not be reasonably pertinent to an inventor trying to develop compounds that inhibit tyrosine kinases, such as those used to treat cancer.

Additionally, the Szmuszkovic *JOC* article is directed to the reaction of indole derivatives with thionyl and sulfuranyl chlorides. This paper does not discuss or suggest any utility for the compounds disclosed therein. It is a process paper that focuses on the reaction of certain indoles with reagents, such as thionyl chloride and sulfuranyl chloride. There is no suggestion or teaching in the reference that the compounds disclosed could be useful as a pharmaceutical agent, let alone as a cancer therapeutic. Applicants contend that this reference would not be within the field of one with ordinary skill in oncology. Applicants also assert that this reference would not be reasonably pertinent to an inventor trying to develop compounds that inhibit tyrosine kinases, such as those used to treat cancer.

For the reasons give above, the '875 patent and the Szmuszkovic *JOC* article would be non-analogous art and therefore should not be cited against the instant invention as allegedly rendering the instant invention obvious. One with ordinary skill in the cancer field would not be motivated to modify the compounds disclosed in the references cited by the Examiner to develop inhibitors of tyrosine kinase. Therefore, Applicants respectfully request that this rejection be withdrawn.

Applicants respectfully contend that Claims 1-6, as amended, are allowable and an early Notice of Allowance is earnestly solicited. If a telephonic communication with Applicants' representative will aid in the advancement of the prosecution of this application, please telephone the representative indicated below.

Respectfully submitted,

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